AF/3761 #

In the United States Patent and Trademark Office

Appellants:	David J. Tyrrell et al.	Docket No.:	16,498
Serial No.:	09/746,872	Group:	3761
Confirmation No.:	9386	Examiner:	J. Webb
Filed:	December 22, 2000	Date:	February 14, 2003

For: ABSORBENT ARTICLES WITH HYDROPHILIC COMPOSITIONS CONTAINING ANIONIC POLYMERS

Appeal Brief Transmittal Letter

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.192, transmitted herewith in triplicate is an Appeal Brief pursuant to the Notice of Appeal which was mailed on December 11, 2002.

Please charge the $320.00 fee, pursuant to 37 C.F.R. 1.17(c), which is due to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. This Appeal Brief Transmittal Letter is submitted in duplicate.

Respectfully submitted,

DAVID J. TYRRELL ET AL.

By: Alyssa A Dudkowski
Alyssa A. Dudkowski
Registration No.: 40,596

CERTIFICATE OF MAILING

I, Cynthia M. Trudell, hereby certify that on February 14, 2003 this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Cynthia M. Trudell
Cynthia M. Trudell

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For: ABSORBENT ARTICLES WITH HYDROPHILIC COMPOSITIONS CONTAINING ANIONIC POLYMERS

Brief on Appeal to the Board of Patent Appeals and Interferences

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.192 Appellants respectfully submit this Brief in support of their Appeal of the **Final Rejection** of claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 that was mailed on September 12, 2002. On December 11, 2002, Appellant, pursuant to 37 C.F.R. 1.191 mailed a timely Notice of Appeal which was received in the Patent Office on December 16, 2002. In accordance with 37 C.F.R. 1.192(a) this Appeal Brief is filed in triplicate.

Real Party in Interest

Kimberly-Clark Worldwide, Inc., the assignee of the present patent application, is the real party in interest.

Related Appeals and Interferences

Applicants submit that there are two (2) related Appeals: (1) a Notice of Appeal was also mailed for co-pending application serial number 09/746,880 (also filed on December 22, 2000); and (2) a Notice of Appeal was also mailed for co-pending application serial number 09/746,888 (also filed on December 22, 2000). These three applications pertain to the same general subject matter and the grounds of final rejection/arguments in response are similar. Further, all three applications are before the same Examiner, Examiner Jamisue Webb.

Status of the Claims

Claims 1-57 are pending in the application.

Claims 8, 9, 35, 36, 42, 44 and 48 are withdrawn from consideration.

Claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 stand rejected and form the subject matter of this appeal.

Status of Amendments Filed Subsequent to Final Rejection

An Amendment After Final was submitted on November 12, 2002. By way of an Advisory Action mailed December 3, 2002, the Examiner considered the request for reconsideration but did not find the application to be in condition for allowance.

Summary of the Invention

In one aspect, the present invention is directed to an absorbent article including an outer cover; a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover; and an absorbent body that is located between the bodyside liner and the outer cover. Further, the article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner. The composition includes: **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol; **(3)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 20 percent by weight of decoupling polymer. **(See, for example, claim 1)**

In another aspect of the present invention, the article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner where the composition includes: **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol; **(3)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof. **(See, for example, claim 20)**

In another aspect of the present invention, the article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner where the composition includes: **(1)** from about 10 to about 80 percent by weight of hydrophilic solvent; **(2)** from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons; **(3)** from about 1 to about 30 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 1 to about 30 percent by weight of C_{14} to C_{30} fatty acid; **(5)** from about 1 to about 10 percent by weight of

emulsifying surfactant having a combined HLB in a range greater than 7; **(6)** from about 0.1 to about 30 percent by weight of natural fats or oils; **(7)** from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; **(8)** from about 0.1 to about 10 percent by weight of emollient; and) **(9)** from about 0.1 to about 20 percent by weight of decoupling polymer. **(See, for example, claim 21)** In a further aspect of the present invention, the article includes a composition including the same components and where the decoupling polymer is selected from: homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof. **(See, for example, claim 39)**.

In another aspect, the present invention is directed to a method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article. The method includes a step of heating a composition to a temperature above the melting point of the composition, where the composition includes: **(1)** hydrophilic solvent; **(2)** high molecular weight polyethylene glycol; **(3)** C_{14} to C_{30} fatty alcohol; **(4)** C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures of such compounds. The composition has a melting point of from about 32°C to about 100°C. The method also includes the steps of applying the composition to the bodyfacing surface of a bodyside liner of an absorbent article and resolidifying the composition. **(See, for example, claim 40)**

In another aspect, the present invention is directed to a method for protecting the skin barrier on a skin surface of a user. The method includes a step of contacting the skin surface of the user with a bodyfacing surface of a liner material. The bodyfacing surface of the liner material includes a composition where the composition includes a hydrophilic solvent, a high molecular weight polyethylene glycol, a C_{14}-C_{30} fatty alcohol, a C_{14}-C_{30} fatty acid and a decoupling polymer. The method also inlcudes a step of maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface. The method further includes a step of repeating contact of the skin surface with the bodyfacing surface of the liner material for a sufficient period of time to protect the skin barrier. More specifically, the composition on the liner material includes: **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol; **(3)** from about 1 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 1 to about 40 percent by weight of

C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof. **(See, for example, claim 54)**

The Issues Presented

In the First Office Action mailed March 18, 2002, the Examiner rejects claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,149,934 issued to Krzysik et al. (hereinafter "the Krzysik patent") in view of U.S. Patent No. 6,238,682 issued to Klofta et al. (hereinafter "the Klofta patent") and further in view of U.S. Patent No. 6,294,186 issued to Beerse et al. (hereinafter "the Beerse patent").

The Examiner believes the Krzysik patent discloses an absorbent article including a topsheet, a backsheet and an absorbent core located in between the topsheet and the backsheet. (See Appendix B for portions of the Krzysik patent cited by the Examiner). The Examiner believes the Krzysik patent discloses a lotion composition on the topsheet where the lotion composition is melted, applied to the topsheet and then cooled. The Examiner also believes that the Krzysik patent discloses a lotion composition having a melting temperature of between 10 and 100 degrees Celsius; a low shear viscosity between 50,000 and 80,000 centipoise; a high shear viscosity between 150 and 200 centipoise; a penetration hardness between 5 and 360 mm; and disposition on the topsheet in an amount of 1-50 grams per square meter. The Examiner acknowledges that the Krzysik patent does not disclose a lotion composition including a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty acid, a fatty alcohol and a decoupling polymer.

The Examiner believes the Klofta patent discloses a lotion composition having 5-60% hydrophilic solvent, a high molecular weight polyethylene glycol and 0.1-60% of a skin conditioning agent (such as fatty alcohols and fatty acids). (See Appendix C for portions of the Klofta patent cited by the Examiner). The Examiner believes it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the composition of the Krzysik patent to be the composition of the Klofta patent in order to provide a lotion composition that kills viruses and imparts a soft lubricious feel. However, the Examiner acknowledges that the Krzysik and Klofta patents fail to disclose the use of a decoupling polymer and a sterol. The Examiner believes the Beerse patent discloses the use of a lotion composition that can be used on diapers and that contains about 0.1 to 10% of a decoupling polymer such as polysaccharides or polyacrylamides and that contains a skin moisturizer such as cholesterol present from 0.1 to 20%. (See Appendix D for portions of the Beerse

patent cited by the Examiner) The Examiner believes it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of the Klofta patent to include the decoupling agent and sterol of the Beerse patent in order to thicken the skin care composition to improve the moisturizing effect of the composition.

In the Appellants's response mailed July 2, 2002, Appellants respond to the Examiner's rejection of the claims over the combination of the Krzysik, Klofta and Beerse patents.

In the Final Office Action mailed September 12, 2002, the Examiner indicates that she did not find the Appellants's arguments of July 2, 2002 to be persuasive. In response to Appellants' argument that the Examiner has not identified why one of ordinary skill in the art would be motivated to combine the disclosures of the Krzysik, Klofta and Beerse patents, the Examiner believes the Krzysik patent discloses the use of lotion on a topsheet. The Examiner also believes the Klofta patent discloses a lotion that is to mitigate the potential for skin irritation. Further, the Examiner believes the Krzysik patent discloses improving skin health. Therefore, the Examiner believes one of ordinary skill in the art would have been motivated to combine the disclosures of the Krzysik and Klofta patents. The Examiner was not persuaded by Appellants' arguments that it would be undesirable to use an antibacterial composition on the bodyside liner (a.k.a. topsheet) of a diaper. The Examiner indicated that a subclass of art has been devoted to the use of antibacterial material on topsheets or in contact with a user's skin in diapers or other absorbent articles. With respect to Appellants' method claims, the Examiner believes the Krzysik patent discloses lotion being located on the topsheet, and while the article is being worn, the lotion is transferred to the skin of the wearer, therefore causing a layer of protection; the Examiner considers this to be a method of protecting the skin.

In the Advisory Action mailed December 3, 2002, the Examiner indicates that she believes the conclusion of obviousness is not based upon improper hindsight reasoning. The Examiner explains that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. The Examiner also explains that so long as the reasoning takes into account only knowledge that was within the level of ordinary skill at the time the invention was made and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. With respect to Appellants' argument that there is no motivation in the Klofta patent to apply the disclosed lotion on a diaper, the Examiner believes the motivation lies in the Krzysik patent. More specifically, the Examiner believes the Klofta patent discloses a lotion used for skin health, the Krzysik patent discloses the use of a diaper with a lotion on it for skin health and therefore, the rejection is based on replacing one lotion for another, both of which are used to improve skin health. With respect to Appellants' argument that the Beerse patent does not provide motivation to put a thickening agent in a

lotion, the Examiner believes the Beerse patent discloses a composition being used in lotions and wipes and therefore, a motivation to combine exists.

1. Whether claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 are unpatentable under 35 U.S.C. § 103 over the Krzysik patent in view of the Klofta and Beerse patents?

A. Specifically, has the Examiner met the burden of establishing a *prima facie* case of obviousness?

1. Has the Examiner met the burden of establishing that there is a suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references and to combine the teachings of the references?

i. Claim Group I: Has the Examiner shown that the suggestion or motivation exists in the references or in the knowledge generally available to one of ordinary skill in the art to modify the references and to combine the teachings of the references to arrive at an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol; **(3)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 20 percent by weight of decoupling polymer?

ii. Claim Group II: Has the Examiner shown that the suggestion or motivation exists in the references or in the knowledge generally available to one of ordinary skill in the art to modify the references and to combine the teachings of the references to arrive at an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 10 to about 80 percent by weight of hydrophilic solvent; **(2)** from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons; **(3)** from about 1 to about 30 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 1 to about 30 percent by weight of C_{14} to C_{30} fatty acid; **(5)** from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7; **(6)** from about 0.1 to about 30 percent by weight of natural fats or oils; **(7)** from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; **(8)** from about 0.1 to about 10 percent by weight of emollient; and **(9)** from about 0.1 to about 20 percent by weight of decoupling polymer?

2. Has the Examiner met the burden of establishing that there would be a reasonable expectation of success? (Claim Groups I and II)

Grouping of the Claims

For the rejections described in Issue 1:

Group I: Claims 1-7, 10-20, 40-41, 43, 45-47 and 49-57 stand or fall as a group.

Group II: Claims 21-34 and 37-39 stand or fall as a group.

The rejected claims do not stand or fall together. The claims should be considered in two groups for the reasons provided in the Argument section below.

Argument

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner bears the initial burden of establishing the *prima facie* case. See In re Piasecki, 223 U.S.P.Q. 785,787, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

1. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Krzysik patent for modifying its teachings with the teachings of the Klofta and Beerse patents.

Claim Group I: Claims 1-7, 10-20, 40-41, 43, 45-47 and 49-57 are directed, in part, to an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol; **(3)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 20 percent by weight of decoupling polymer. None of the three cited references (the Krzysik patent; the Klofta patent; and the Beerse patent) discloses the claimed composition applied to a bodyside liner of an absorbent article. The Examiner improperly "picked and choosed" the components from the three references using the claimed invention as a template in order to form the rejection.

In the Office Action mailed March 18, 2002, the Examiner states "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Krzysik to be the composition of Klofta, in order to provide a lotion composition that kills viruses and imparts a soft lubricious feel." The Examiner also states "It would have been obvious to one having

ordinary skill in the art at the time the invention was made to have [sic] modify the composition of Klofta to include the decoupling agent and the sterol of Beerse, in order to thicken the skin care composition to improve the moisturizing effect of the composition." In the Final Office Action mailed September 12, 2002, the Examiner states "With respect to applicant's arguments that one of ordinary skill in the art would not be motivated to combine disclosures of a diaper and tissue papers: Krzysik discloses the use of lotion on a topsheet, and Klofta discloses a lotion that is to mitigate the potential for skin irritation, Krzysik discloses to improve skin health, therefore one of ordinary skill in the art would have motivation to combine the two." In the Advisory Action mailed December 3, 2002, the Examiner states "The motivation for a lotion being in a diaper is located already in the Krzysik patent, the Klofta [sic] discloses a lotion used for skin health, Krzysik discloses the use of a diaper with a lotion on it for skin health, therefore the rejection is simply replacing one lotion for another, both of which are used to improve skin health." The Examiner also states "With respect to the applicant's arguments that Beerse does not provide motivation to put the thickening agent in a lotion: Beerse in column 4, lines 3-4 disclose the composition being used in lotions and wipes, therefore there exist a motivation to combine." In the First Office Action, the Final Office Action and the Advisory Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The Examiner does not adequately state why one of ordinary skill would read the Krzysik patent and then look to the Klofta patent and select particular compounds and then further look to the Beerse patent to select additional particular compounds to arrive at the composition of claims 1-7, 10-20, 40-41, 43, 45-47 and 49-57.

Claim Group I includes claims directed, in part, to absorbent articles with compositions including five components: (1) hydrophilic solvent; (2) high molecular weight polyethylene glycol; (3) C_{14} to C_{30} fatty alcohol; (4) C_{14} to C_{30} fatty acid; and (5) decoupling polymer. The Krzysik patent discloses an absorbent article having a lotionized bodyside liner, but as acknowledged by the Examiner, the Krzysik patent does not disclose a lotion composition that includes a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty acid, a fatty alcohol and a decoupling polymer. (See Office Action mailed March 18, 2002, page 4). The Klofta patent is directed to anhydrous skin lotions having antimicrobial components for application to tissue paper. The Examiner relies on the Klofta patent as disclosing hydrophilic solvents (at col. 5, lines 6-8), a high molecular weight polyethylene glycol (at col. 10, lines 9-10) and "skin conditioning agents" such as fatty alcohols and fatty acids (at col. 18, line 10 to col. 19, line 24). (See Appendix C to this Appeal Brief for these portions of the Klofta patent.) The Examiner acknowledges that the Klofta patent does not disclose a composition including a decoupling polymer. In order to show "disclosure" of a decoupling polymer, the Examiner relies on the Beerse patent which is directed to antimicrobial compositions including a benzoic acid analog and a metal salt.

The Examiner believes the Beerse patent discloses the decoupling polymers of the present invention at Col. 36, line 51 to Col. 37, line 46 (polysaccharides or polyacrylamides). (See Appendix D to this Appeal Brief for this portion of the Beerse patent.)

The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner believes that one of skill in the art would simply replace the lotion of the Krzysik patent with the lotion of the Klofta patent. However, the Examiner does not explain why one of skill in the art would pick and choose components from the Klofta patent to form a lotion for diapers. The Klofta patent does not disclose all of the lotion components claimed by the present invention and the compositions disclosed by the Klofta patent include components not claimed by the present invention (e.g. "antimicrobials" are the key active ingredients of the Klofta compositions; see Col. 11, lines 16-20). Therefore, one of skill in the art would not be able to simply replace the lotion of the Krzysik patent with a composition from the Klofta patent. Similarly, one of skill in the art could not simply apply the compositions of the Beerse patent to a diaper to arrive at the claimed invention. The Examiner had to select polysaccharides/polyacrylamides (disclosed as suitable "decoupling polymers" for the present invention) from thousands of compounds disclosed as possible components of the antimicrobial compositions of the Beerse patent. The Examiner has failed to identify how the cited references suggest the desirability of modifying the compositions of the Krzysik patent to include components from the Klofta and Beerse patents. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of the compositions of Claim Group I from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)[1]. For at least these reasons, Appellants assert that a *prima facie* case of obviousness has not been made and that the claims of Claim Group I are separately patentable over the references.

Claim Group II: Claims 21-34 and 37-39 are directed to an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition

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[1] "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

includes **(1)** from about 10 to about 80 percent by weight of hydrophilic solvent; **(2)** from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons; **(3)** from about 1 to about 30 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 1 to about 30 percent by weight of C_{14} to C_{30} fatty acid; **(5)** from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7; **(6)** from about 0.1 to about 30 percent by weight of natural fats or oils; **(7)** from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; **(8)** from about 0.1 to about 10 percent by weight of emollient; and **(9)** from about 0.1 to about 20 percent by weight of decoupling polymer. As compared to Claim Group I, the compositions of Claim Group II include the additional components of an emulsifying surfactant having a combined HLB in a range greater than 7, natural fats or oils, sterols or sterol derivatives and an emollient. The Examiner believes the Klofta patent discloses emulsifying surfactants having a combined HLB in a range greater than 7 (at Col. 21, lines 12-14), natural fats or oils (at Col. 27, lines 30-37) and emollients (at Col. 18, lines 10-12) and the Examiner believes the Beerse patent discloses sterols or sterol derivatives (at Col. 10, line 43 to Col. 11, line 16). However, for the same reasons as those stated above, the Examiner does not identify how the references suggest the desirability of modifying the Krzysik patent compositions to include these additional components from the Klofta and Beerse patents. For at least these reasons, Appellants assert that a *prima facie* case of obviousness has not been made and that the claims of Claim Group II are separately patentable over the references.

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the compositions of the Krzysik patent to include components from the Klofta and Beerse patents.

One of the benefits of the compositions of the present invention is their ability to reduce the irritation response of the skin when the skin is exposed to fecal protease and bile acid insults. (See pages 57-62 of the Specification as filed; copy provided as Appendix E to this Appeal Brief). In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor of reducing the irritation response of skin exposed to fecal proteases and bile acids. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success at reducing irritation response. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The Beerse patent relates to antimicrobial compositions that provide immediate as well as residual anti-viral and antibacterial efficacy. (See Col. 1, lines 44-46). The Examiner does not explain why one of skill in the art would have been motivated to select the "thickening agents" of the Beerse patent to be used in the lotion compositions of the Klofta patent- particularly in view of the large number of groups of compounds disclosed in the Beerse patent- for the purpose of reducing skin irritation response to fecal proteases and bile acids. Therefore, there would have been no expectation of success at arriving at a composition that reduces the irritation response of skin to the enzymes in biological fluids as occurs with the compositions claimed by the present invention. Additionally, none of the cited references recognize the "result-effective" capability of the decoupling polymers of the present invention.

In view of the above Arguments, it is respectfully submitted that the rejection of claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 under 35 U.S.C. § 103 are in error. Accordingly, Appellants respectfully request that the Examiner's rejection be reversed. Please charge the $320.00 fee, pursuant to 37 C.F.R. 1.17(f), for filing this Appeal Brief to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. Any additional prosecutional fees which are due may also be charged to deposit account number 11-0875.

The undersigned may be reached at: (920) 721-2433.

Respectfully submitted,

DAVID J. TYRRELL ET AL.

By: Alyssa A Dudkowski

Alyssa A. Dudkowski
Registration No.: 40,596

CERTIFICATE OF MAILING

I, Cynthia M. Trudell, hereby certify that on February 14, 2003 this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Cynthia M. Trudell

Cynthia M. Trudell

Appendix A – The Claims On Appeal

1. An absorbent article comprising:

   (a) an outer cover;

   (b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

   (c) an absorbent body that is located between the bodyside liner and the outer cover; and

   (d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 10 to about 90 weight percent of hydrophilic solvent, from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol, from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol, from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid and from about 0.1 to about 20 percent by weight of decoupling polymer.

2. The absorbent article of claim 1, wherein the composition has a high shear viscosity less than about 5,000 centipoise at a temperature greater than about 60°C and has a low shear viscosity greater than about 50,000 centipoise at a temperature of about 55°C.

3. The absorbent article of claim 1, wherein the hydrophilic solvent of the composition is selected from water, propylene glycol, low molecular weight polyethylene glycol, glycerin, hydrogenated starch hydrolysate, methoxyisopropanol, PPG-2 propyl ether, PPG-2 butyl ether, PPG-2 methyl ether, PPG-3 methyl ether, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, propylene carbonate, water soluble/dispersible polypropylene glycols, ethoxylated polypropylene glycol, sorbitol, silicone glycols and mixtures thereof.

4. The absorbent article of claim 1, wherein the molecular weight of the high molecular weight polyethylene glycol is from about 720 to about 1,840,000 daltons.

5. The absorbent article of claim 1, wherein the molecular weight of the high molecular weight polyethylene glycol is from about 1,400 to about 440,000 daltons.

6. The absorbent article of claim 1, wherein the fatty alcohol of the composition is selected from cetyl alcohol, stearyl alcohol, arachidyl alcohol, behenyl alcohol and mixtures thereof.

7. The absorbent article of claim 1, wherein the decoupling polymer of the composition is selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl

alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

8. (Withdrawn)

9. (Withdrawn)

10. The absorbent article of claim 1, wherein the composition further includes from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7.

11. The absorbent article of claim 10, wherein the emulsifying surfactant is selected from glyceryl stearate SE, glycol stearate SE, water dispersible metal soaps, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80 and mixtures thereof.

12. The absorbent article of claim 1, wherein the composition further includes from about 0.1 to about 30 percent by weight of natural fats or oils.

13. The absorbent article of claim 12, wherein the natural fat or oil is selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Benenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

14. The absorbent article of claim 1, wherein the composition further includes from about 0.1 to about 10 percent by weight of sterols or sterol derivatives.

15. The absorbent article of claim 14, wherein the sterol or sterol derivative is selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C10-C30 cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

16. The absorbent article of claim 1, wherein the composition further includes from about 0.1 to about 10 percent by weight of emollient.

17. The absorbent article of claim 16, wherein the emollient is selected from petroleum based oils, petrolatum, mineral oils, alkyl dimethicones, alkyl methicones, phenyl silicones, alkyl trimethylsilanes, dimethicone, lanolin, fatty alcohols and mixtures thereof.

18. The absorbent article of claim 1, wherein the composition further includes from about 0.5 to about 10 percent by weight of a rheology modifier.

19. The absorbent article of claim 18, wherein the rheology modifier is selected from natural clays, synthetic analogs of natural clays, starches, alginates, natural gums and mixtures thereof.

20. An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 10 to about 90 weight percent of hydrophilic solvent, from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol, from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol, from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid and from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

21. An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 10 to about 80 percent by weight of hydrophilic solvent, from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons, from about 1 to about 30 percent by weight of C14 to C30 fatty alcohol, from about 1 to about 30 percent by weight of C14 to C30 fatty acid, from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7, from about 0.1 to about 30 percent by weight of natural fats or oils, from about 0.1 to about 10 percent by weight of sterols or sterol

derivatives, from about 0.1 to about 10 percent by weight of emollient and from about 0.1 to about 20 percent by weight of decoupling polymer.

22. The absorbent article of claim 21, wherein the composition has a melting point from about 32 °C to about 100 °C.

23. The absorbent article of claim 21, wherein the composition has a high shear viscosity less than about 5,000 centipoise at a temperature greater than about 60°C and has a low shear viscosity greater than about 50,000 centipoise at a temperature of about 55°C.

24. The absorbent article of claim 21, wherein the composition has a penetration hardness of from about 5 millimeters to about 365 millimeters at 25°C.

25. The absorbent article of claim 21, wherein the composition is on the bodyfacing surface in an amount of from about 0.1 grams per meter squared (g/m2) to about 30 g/m2.

26. The absorbent article of claim 21, wherein the hydrophilic solvent of the composition is selected from water, propylene glycol, low molecular weight polyethylene glycol, glycerin, hydrogenated starch hydrolysate, methoxyisopropanol, PPG-2 propyl ether, PPG-2 butyl ether, PPG-2 methyl ether, PPG-3 methyl ether, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, propylene carbonate, water soluble/dispersible polypropylene glycols, ethoxylated polypropylene glycol, sorbitol, silicone glycols and mixtures thereof.

27. The absorbent article of claim 21, wherein the molecular weight of the high molecular weight polyethylene glycol is from about 720 to about 1,840,000 daltons.

28. The absorbent article of claim 21, wherein the molecular weight of the high molecular weight polyethylene glycol is from about 1,400 to about 440,000 daltons.

29. The absorbent article of claim 21, wherein the fatty alcohol of the composition is selected from cetyl alcohol, stearyl alcohol, arachidyl alcohol, behenyl alcohol and mixtures thereof.

30. The absorbent article of claim 21, wherein the emulsifying surfactant of the composition is selected from glyceryl stearate SE, glycol stearate SE, water dispersible metal soaps, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80 and mixtures thereof.

31. The absorbent article of claim 21, wherein the natural fat or oil of the composition is selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed

Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Benenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

32. The absorbent article of claim 21, wherein the sterol or sterol derivative of the composition is selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C10-C30 cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

33. The absorbent article of claim 21, wherein the emollient of the composition is selected from petroleum based oils, petrolatum, mineral oils, alkyl dimethicones, alkyl methicones, phenyl silicones, alkyl trimethylsilanes, dimethicone, lanolin, fatty alcohols and mixtures thereof.

34. The absorbent article of claim 21, wherein the decoupling polymer of the composition is selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

35. (Withdrawn)

36. (Withdrawn)

37. The absorbent article of claim 21, wherein the composition further includes from about 0.5 to about 10 percent by weight of a rheology modifier.

38. The absorbent article of claim 37, wherein the rheology modifier is selected from natural clays, synthetic analogs of natural clays, alginates, starches, natural gums and mixtures thereof.

39. An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 10 to about 90 percent by weight of hydrophilic solvent, from about 10 to

about 90 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons, from about 1 to about 30 percent by weight of a C_{14} to C_{30} fatty alcohol, from about 1 to about 30 percent by weight of a C_{14} to C_{30} fatty acid, from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7, from about 0.1 to about 30 percent by weight of natural fats or oils, from about 0.1 to about 10 percent by weight of sterols or sterol derivatives, from about 0.1 to about 10 percent by weight of emollient and from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

40. A method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article comprising the steps of:

    (a) heating a composition comprising hydrophilic solvent, high molecular weight polyethylene glycol, C_{14} to C_{30} fatty alcohol, C_{14} to C_{30} fatty acid and from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures of such compounds, to a temperature above the melting point of the composition, the composition having a melting point of from about 32° C to about 100° C;

    (b) applying the composition to the bodyfacing surface of a bodyside liner of an absorbent article; and

    (c) resolidifying the composition.

41. The method of claim 40, wherein after the step of resolidification, the composition has a low shear viscosity of greater than about 50,000 centipoise.

42. (Withdrawn)

43. The method of claim 40, wherein after the step of heating, the composition is applied by slot coating.

44. (Withdrawn)

45. The method of claim 40, wherein the hydrophilic solvent of the composition is from about 10 to about 90 percent by weight of the composition and is selected from water, propylene glycol, low

molecular weight polyethylene glycol, glycerin, hydrogenated starch hydrolysate, methoxyisopropanol, PPG-2 propyl ether, PPG-2 butyl ether, PPG-2 methyl ether, PPG-3 methyl ether, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, propylene carbonate, water soluble/dispersible polypropylene glycols, ethoxylated polypropylene glycol, sorbitol, silicone glycols and mixtures thereof.

46. The method of claim 40, wherein the high molecular weight polyethylene glycol is from about 10 to about 90 percent by weight of the composition and is selected from polyethylene glycols having a molecular weight of from about 720 to about 1,840,000 daltons.

47. The method of claim 40, wherein the fatty alcohol of the composition is from about 0 to about 40 percent by weight of the composition and is selected from cetyl alcohol, stearyl alcohol, arachidyl alcohol, behenyl alcohol and mixtures thereof.

48. (Withdrawn)

49. The method of claim 40, wherein the composition further includes from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7 selected from glyceryl stearate SE, glycol stearate SE, water dispersible metal soaps, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80 and mixtures thereof.

50. The method of claim 40, wherein the composition further includes from about 0.1 to about 30 percent by weight of natural fats or oils selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Benenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

51. The method of claim 40, wherein the composition further includes from about 0.1 to about 10 percent by weight of sterols or sterol derivatives selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C10-C30 cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

52. The method of claim 40, wherein the composition further includes from about 0.1 to about 10 percent by weight of emollient selected from petroleum based oils, petrolatum, mineral oils, alkyl dimethicones, alkyl methicones, phenyl silicones, alkyl trimethylsilanes, dimethicone, lanolin, fatty alcohols and mixtures thereof.

53. The method of claim 40, wherein the composition further includes from about 0.5 to about 10 percent by weight of a rheology modifier selected from natural clays, synthetic analogs of natural clays, starches, alginates, natural gums and mixtures thereof.

54. A method for protecting the skin barrier on a skin surface of a user, comprising the steps of:

a) contacting the skin surface of the user with a bodyfacing surface of a liner material, the bodyfacing surface having a composition comprising a hydrophilic solvent, a high molecular weight polyethylene glycol, a C_{14}-C_{30} fatty alcohol, a C_{14}-C_{30} fatty acid and a decoupling polymer;

b) maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface; and

c) repeating the contact of the skin surface with the bodyfacing surface of the liner material for a sufficient period of time to protect the skin barrier,

wherein the composition comprises from about 10 to about 90 percent by weight of hydrophilic solvent, from about 10 to about 90 percent by weight of high molecular weight polyethylene glycol, from about 1 to about 40 percent by weight of a C_{14} to C_{30} fatty alcohol, from about 1 to about 40 percent by weight of a C_{14} to C_{30} fatty acid and from about 0.1 to about 20 percent by weight of a decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures thereof.

55. The method of claim 54, wherein the composition has a melting point from about 32°C to about 100°C.

56. The method of claim 54, wherein the composition has a high shear viscosity less than about 5,000 centipoise at a temperature greater than about 60°C and has a low shear viscosity greater than about 50,000 centipoise at a temperature of about 55°C.

57. The method of claim 54, wherein the composition has a penetration hardness of from about 5 millimeters to about 365 millimeters at 25°C.

Appendix B

Portions of the Krzysik patent cited by the Examiner:

Col. 13, line 64 to Col. 14, line 3:

For example, the lotion formulation may be applied to the bodyside liner **34** by (a) heating the lotion formulation to a temperature above the melting point of the formulation, causing the formulation to melt, (b) uniformly applying the

melted formulation to the bodyfacing surface **52** of the bodyside liner **34**; and (c) resolidifying the deposits of the melted formulation. Desirably, resolidification of the deposits occurs almost instantaneously, without the need for external cooling means such as chill rolls. This can occur if the formulation is heated to a temperature only slightly above or at the melting point of the formulation. However,

Col. 12, lines 31-34:

Moreover, to provide the improved stability and transfer to the skin of the wearer, the lotion formulation of the present invention may define a melting point of from about 30° C. to about 100° C., desirably from about 35° C. to about 80° C., and more desirably from about 40° C. to about 75° C. Lotion formulations which have lower melting points exhibit migration of the lotion during use and at elevated

Col. 12, lines 42-60:

The lotion formulation of the present invention may further define a melt point viscosity of from about 50 to about 1000000 centipoise, desirably from about 50000 to about 800000 centipoise, and more desirably from about 100000 to about 500000 centipoise for reduced migration and improved transfer to the skin of the wearer. Lotion formulations which have lower melt point viscosities exhibit migration of the lotion through the bodyside liner **34** into the absorbent body **26** of the article which can undesirably result in reduced transfer to the skin. Whereas, lotion formulations which have higher melt point viscosities may be so solid as to also exhibit a reduced transfer to the skin.

Further, to provide the improved stability and transfer to the skin of the wearer, the lotion formulation of the present invention may also define a viscosity of from about 50 to about 10000 centipoise, desirably from about 100 to about 500 centipoise, and more desirably from about 150 to about 250 centipoise at a temperature of 60° C. Lotion formulations which have lower viscosities at 60° C. exhibit migration of the lotion through the bodyside liner **34** into the absorbent body **26** of the article which can undesirably result in reduced transfer to the skin. Whereas, lotion formulations which have higher viscosities at 60° C. may be so solid as to also exhibit a reduced transfer to the skin.

Col. 12, lines 66-67

to also exhibit a reduced transfer to the skin.

The penetration hardness of the lotion formulations of this invention can be from about 5 to about 360 millimeters,

Col. 13, lines 44-49

The lotion formulation can be applied to the bodyside liner **34** at any add-on level which provides the desired transfer benefit. For example, the total add-on level of the lotion formulation can be from about 0.05 to about 100 mg/cm^2, desirably from about 1 to about 50 mg/cm^2 and more desirably from about 10 to about 40 mg/cm^2 for improved performance. The add-on amount will depend upon the desired effect of the lotion on the product attributes and the specific lotion formulation. As discussed above, the improved stability and reduced tendency to migrate of the

Appendix C

Portions of the Klofta patent cited by the Examiner as disclosing: "a lotion composition with a 5-60% hydrophilic solvent, a high molecular weight polyethylene glycol [and] 0.1-60% skin conditioning agent such as a fatty alcohols and fatty acids."

Col. 5, lines 6-8 ("hydrophilic solvent"):

Optionally, an inorganic acid may be added in conjunction with the organic acid to adjust pH. The optional inorganic acid may comprise from about 0.1% to 5% of the lotion composition.

The antibacterial component of the lotion comprises from about 0.1% to 6% of the lotion composition. The hydrophilic solvent which comprises from about 5% to 60% of the lotion composition, preferably has from about 1 to 150 carbon atom(s) wherein the carbon atom(s) are either branched or straight chained, saturated or unsaturated, with or without ether linkages and contains from about 1 to 302 hydroxyl group(s).

Col. 10, lines 9-10 ("high molecular weight polyethylene glycols":

lotion compositions can have the appearance of a semi-solid but can be made to flow as the shear rate is increased. This is due to the fact that, while the semisolid or solid lotion compositions contain primarily solid components, they may also include some minor liquid components.

The solid or semisolid consistency of the lotions at room temperature are due to the addition of high melting components such as those high melting organic acids having antiviral functionality; fatty alcohols; waxes; high molecular weight polyethylene glycols; polyoxyethylene mono-, di-, and tri-sorbitan alkylates; mono-, di-, and tri- sorbitan alkylates; and non-ionic ethoxylated surfactants. The high melting and higher molecular weight alkane fraction of petrolatum, which may be used as a skin conditioning agent in the present invention, can also contribute to raising the melting point of these lotions. These higher molecular weight components of petrolatum are typically high molecular weight waxy-type hydrocarbons.

Col. 18, line 10 to Col. 19, line 24 ("fatty alcohols and fatty acids"):

Skin conditioning agents useful in the present invention can be petroleum-based such as mineral oil and petrolatum, fatty acid ester type, fatty alcohol type, dimethicones including functionalized derivatives of dimethicones, polyethylene glycols, or mixtures of these skin conditioning agents. Suitable petroleum-based skin conditioning agents include those hydrocarbons, or mixtures of hydrocarbons, having chain lengths of from 16 to 32 carbon atoms. Petroleum based hydrocarbons having these chain lengths include mineral oil (also known as "liquid petrolatum") and petrolatum (also known as "mineral wax," "petroleum jelly" and "mineral jelly"). Mineral oil usually refers to less viscous mixtures of hydrocarbons which are liquids at room temperature. Petrolatum usually refers to more viscous mixtures of hydrocarbons having from 16 to 32 carbon atoms. Petrolatum is a particularly preferred skin conditioning agent for lotion compositions of the present invention because of its exceptional skin moisturizing benefits.

Dimethicones and functionalized derivatives of dimethicones are also very effective paper softeners. The amino-functional polydimethylsiloxanes are especially effective softeners for paper. Dimethicones possessing a viscosity range of about 20 to 12,500 centistokes at 25° C. are preferred. Thus, not only could a material such as dimethicone or the other skin conditioning agents mentioned above provide a soft feel to the paper and skin, but they could provide a skin protectant benefit if transferred to the skin. This benefit would be particularly advantageous if it was desirable to prevent a particularly harsh ingredient from contacting the skin.

Fatty alcohols are also particularly preferred due to their crystalline linear structure. The high melt points of the fatty alcohols raises the melt point of the lotion and thus aids in preventing migration of the lotion throughout the fiber network. The linear structure of the fatty alcohols gives the lotion crystalline attributes and should lead to faster crystallization/solidification onto the paper substrate surface. Thus, during application to the paper surface, the lotion should set up and solidify faster on the surface of the paper substrate. This concentrates the lotion at the surface and gives the lotioned paper product a superior feel and also leads to a more efficient use of the antimicrobial(s). The hydroxyl group in the fatty alcohol may also contribute to the lotion's antimicrobial action.

Suitable fatty acid ester type skin conditioning agents include those derived from C_{12}–C_{28} fatty acids, preferably C_{16}–C_{22} saturated fatty acids, and short chain (C_1–C_8, preferably C_1–C_3) monohydric alcohols. Representative examples of such esters include methyl palmitate, methyl stearate, isopropyl laurate, isopropyl myristate, isopropyl palmitate, ethylhexyl palmitate and mixtures thereof. Suitable fatty acid ester skin conditioning agents can also be derived from esters of longer chain fatty alcohols (C_{12}–C_{28}, preferably C_{12}–C_{18}) and shorter chain fatty acids e.g., lactic acid, such as lauryl lactate and cetyl lactate.

In addition to the petroleum-based skin conditioning agents, dimethicone based skin conditioning agents, fatty acid ester skin conditioning agents, and fatty alcohol skin

conditioning agents, the skin conditioning agents useful in the present invention can include minor amounts (e.g., up to about 10% of the total skin conditioning agent) of other, conventional skin conditioning agents. These other, conventional skin conditioning agents include propylene glycol, glycerin, hexylene glycol, polyethylene glycols, triethylene glycol, liposomes, spermaceti, squalene, cholesteryl, or other waxes (such as the C_{12} to C_{50} waxes), fatty acids, and fatty alcohol ethers having from 12 to 28 carbon atoms in their fatty chain, such as stearic acid, propoxylated fatty alcohols; glycerides, acetoglycerides, and ethoxylated glycerides of C_{12}–C_{28} fatty acids; other fatty esters of polyhydroxy alcohols; lanolin and its derivatives; silicone polyether copolymers, and polysiloxanes such as amino-functional polydimethylsiloxanes having a viscosity at 20° C. of from about 5 to about 2,000 centistokes such as disclosed in U.S. Pat. No. 5,059,282, issued to Ampulski et al. on Oct. 22, 1991, which is incorporated by reference.

The amount of skin conditioning agent that can be included in the lotion composition will depend on a variety of factors, including the particular skin conditioning agent involved, the lotion-like benefits desired, the other components in the lotion composition and like factors. The lotion composition can comprise from about 0.1% to about 60% of the skin conditioning agent, more preferably from about 5% to about 50%.

Col. 21, lines 12-14 ("surfactant with an HLB value of greater than 7"):

while others are not.

Suitable nonionic surfactants will be substantially nonmigratory after the lotion composition is applied to the tissue paper web and will typically have HLB values in the range of from about 4 to about 20, preferably from about 7 to about 20. To be nonmigratory, these nonionic surfactants will typically have melt temperatures greater than the tempera-

Appendix D

Portions of the Beerse patent cited by the Examiner as disclosing: "a lotion composition that can be used on diapers that contains about 0.1-10% of a decoupling polymer such as polysaccharides or polyacrylamides."

Col. 9, lines 12-13:

tion. The cleansing compositions can optionally contain, at their art-established levels, other materials which are conventionally used in cleansing compositions.

Additional carriers suitable for the compositions of the present invention may include various substrate-based products. In such instances, the present compositions may be impregnated into or onto the substrate products and may be allowed to remain wet or may be subjected to a drying process. For instance, suitable carriers include, but are not limited to, dry and wet wipes suitable for personal care and household use (e.g., nonwoven baby wipes, household cleaning wipes, surgical preparation wipes, etc.); diapers; infant changing pads; dental floss; personal care and household care sponges or woven cloths (e.g., washcloths, towels, etc.); tissue-type products (e.g. facial tissue, paper towels, etc.); and disposable garments (e.g., gloves, smocks, surgical masks, infant bibs, socks, shoe inserts, etc.).

Col. 36, line 51 to Col. 37, line 46:

The thickener is preferably present at a concentration of from about 0.01% to about 10%, preferably from about 0.1% to about 5%, and most preferably from about 0.1% to about 3%. Mixtures of the above thickeners may also be used.

Lipophilic skin moisturizing agents/temollients may also be incorporated into the water or alcohol based solutions and gels. Examples of suitable lipophilic skin moisturizers include, but are not limited to, petroleum, mineral oil, micro-crystalline waxes, polyalkenes, paraffin, cerasin, ozokerite, polyethylene, perhydrosqualene, dimethicones, cyclomethicones, alkyl siloxanes, polymethylsiloxanes, methylphenylpolysiloxanes, hydroxylated milk glyceride, castor oil, soy bean oil, maleated soy bean oil, safflower oil, cotton seed oil, corn oil, walnut oil, peanut oil, olive oil, cod liver oil, almond oil, avocado oil, palm oil, sesame oil, liquid sucrose octaesters, blends of liquid sucrose octaesters and solid polyol polyesters, lanolin oil, lanolin wax, lanolin alcohol, lanolin fatty acid, isopropyl lanolate, acetylated lanolin, acetylated lanolin alcohols, lanolin alcohol linoleate, lanolin alcohol riconoleate, beeswax, beeswax derivatives, spermaceti, myristyl myristate, stearyl stearate, carnauba and candelilla waxes, cholesterol, cholesterol fatty acid esters and homologs thereof, lecithin and derivatives, Sphingolipids, ceramides, glycosphingo lipids and homologs thereof, and mixtures thereof. A more detailed discussion of useful lipophilic skin moisturizers can be found in U.S. Pat. No. 5,716,920 to Glenn, Jr. et al., issued Feb. 10, 1998, herein incorporated by reference in its entirety.

Also useful as a lipophilic skin moisturizing agent are liquid nondigestible oils such as those described in U.S. Pat. Nos. 3,600,186 to Mattson; Issued Aug. 17, 1971 and 4,005,195 and 4,005,196 to Jandacek et al; both issued Jan. 25, 1977, all of which are herein incorporated by reference, or blends of liquid digestible or nondigestible oils with solid polyol polyesters such as those described in U.S. Pat. No. 4,797,300 to Jandacek; issued Jan. 10, 1989; U.S. Pat. Nos. 5,306,514, 5,306,516 and 5,306,515 to Letton; all issued Apr. 26, 1994, all of which are incorporated by reference herein in their entireties.

When incorporated into the solutions or gels, the lipophilic skin moisturizer is present at concentrations of from about 0.1% to about 20%, preferably from about 1% to about 15%, more preferably from about 2% to about 10% by weight.

Col. 10, line 43 to Col. 11, line 16:

The thickener is preferably present at a concentration of from about 0.01% to about 10%, preferably from about 0.1% to about 5%, and most preferably from about 0.1% to about 3%. Mixtures of the above thickeners may also be used.

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Appendix E – Pages 57-62 of the Specification as filed.

In order to evaluate the efficacy of the compositions of the invention, a human skin culture was selected to model the response of the human epidermis. EPIDERM skin culture is a cornified, air-interfaced human skin culture. EPIDERM skin culture has multiple layers of progressively differentiated keratinocytes resembling human epidermis. EPIDERM EPI-200 skin culture can be purchased from MatTek Corporation of Ashland, MA. Experiments using EPIDERM skin culture are conducted in six well plates. Typically, five EPIDERM skin culture inserts are added to five of the six wells. Each well contains one milliliter of pre-warmed media that is the same as the EPIDERM skin culture media. The plates are then incubated in a 37°C, 5% CO_2 incubator for thirty minutes. After incubation, 15 microliters of test composition or control are applied to the surface of the EPIDERM skin culture after removing any residual media. The well plates, with the test compositions/control applied, are incubated in the 37°C, 5% CO_2 incubator for thirty minutes after which the underlying media is removed and replaced with fresh, pre-warmed media. Next, ten microliters of insult solution, either fecal protease or bile acid, are applied to the surface of the EPIDERM skin culture.

The insult solution is prepared by diluting a 10 mg/ml stock solution in phosphate-buffered saline to a working concentration of 250 g / ml. The base of the stock solution is 50 mM NaOAcetate, pH 5.5 and 0.15 M NaCl stored at -80°C. One milliliter of the stock protease insult solution contains 2558 USP units of trypsin and 298 USP units of chymotrypsin and is available from Specialty Enzymes, Inc. of Chino, CA. The bile acid insult solution can be prepared by dissolving 65 mg of cholic acid, 62 mg of deoxycholic acid and 31 mg of chenodeoxycholic acid in 10 ml of phosphate-buffered saline. The bile acid insult components can be purchased from Sigma Chemical Co. of St. Louis, MO. Phosphate-buffered saline, pH 7.4 (hereinafter "PBS") can be purchased from Life Technologies of Rockville, Maryland.

Infant feces contain proteases that include trypsin and chymotrypsin (See Haverback, B. J., Dyce, B.J., Gutentag, P.J., and Montgomery, D. W. (1963) Measurement of Trypsin and Chymotrypsin in Stool. Gasteroenterology 44:588-597; and Barbero, G.J., Sibinga, M.S., Marino, J. M., and Seibel, R. (1966) Stool Trypsin and Chymotrypsin. Amer. J. Dis. Child 112:536-540). For internal studies, infant feces were collected and the amount of total protease and trypsin activities determined for each of the fecal extracts. To prepare the extract, the feces were suspended in water and vigorously vortexed. After vortexing, the samples were held on ice prior to centrifugation at 15,000 times the force of gravity for 20 minutes. The supernatant was filtered through 0.22 micron cellulose acetate filters and stored at -80°C until use. The amount of trypsin

activity in the fecal extracts ranged from 0.4-402 μg/ml (n=19) as measured by the ability of the sample to hydrolyze a fluorescently-labeled trypsin peptide substrate (Boc-Gln-Ala-Arg-AMC HCl, BACHEM California, Incorporated, Torrance, CA). Total protease activity was measured as the ability of the sample to hydrolyze a fluorescent dye-labeled casein substrate (EnzChek Protease Assay Kit (E-6639), Molecular Probes, Eugene, OR). Irritation induced in the EPIDERM skin culture correlated with the total protease as well as trypsin activities of the fecal extracts. Based on the literature sources as well as internal data, a trypsin-chymotrypsin insult was chosen as representative of a fecal insult, specifically a fecal protease insult, for the examples that follow.

After application of the insult solution, the well plates are incubated for six hours in the 37°C, 5% CO_2 incubator. At the end of six hours, the well plates are removed from the incubator, the underlying media is removed and stored at -80°C. The response of the EPIDERM skin culture to the test compositions/control and the insult solution is determined by measuring the amount of interleukin-1 alpha (hereinafter "IL-1 "). Interleukin-1 alpha can be quantified using an Interleukin-1 alpha Quantikine Kit available from R&D Systems of Minneapolis, Minnesota. Interleukin-1 alpha measurements are converted to Log_{10} for each of the treatments and the averages for each treatment are calculated. In order to determine the ability of the test compositions to reduce skin irritation caused by the biological insults, the percent mean reduction of IL-1 is calculated as follows:

$$\% \text{ mean reduction of IL-1} = 100 \times \frac{\text{((control + insult) result - (test composition + insult) result)}}{\text{((control + insult) result - (control + PBS) result)}}$$

(Test composition + insult) result = the measured amount of IL-1 from treatment with a test composition + insult.

(Control + insult) result = the measured amount of IL-1 from a treatment with water or PBS + insult.

(Control + PBS) result = the measured amount of IL-1 from a treatment with water or PBS + PBS.

The greater the % mean reduction of IL-1 , the more effective a composition is at reducing irritation caused by the biological insult (proteases or bile acids).

In order to insure that the test compositions/control do not affect the viability of the EPIDERM skin culture, a MTT assay is run. The MTT dye is taken up by the cells. The

reduction of the dye as a result of cellular metabolism can be used to measure the cytotoxicity of the test compositions. In order to confirm viability, inserts of the EPIDERM skin culture that have already been subjected to the test compositions and biological insults are removed from their media and are washed consecutively through immersion in three different beakers of PBS. Fresh PBS is used for each test composition or control being evaluated. The PBS is discarded onto paper towel. The EPIDERM skin culture inserts are then patted onto paper towel and placed into the wells of a 24 well plate containing 300 microliters of pre-warmed media. After all of the EPIDERM skin culture inserts are washed, they are transferred to new 24 well plates containing 300 microliters of the MTT reagent. The MTT reagent is thiazolyl blue having the formula 3-[4,5-Dimethylthiazol-2-yl]-2,5-diphenyltetrzoliumbromide. The plates are incubated for 2 hours in a 37°C, 5% CO_2 incubator. After incubation, the EPIDERM skin culture inserts are transferred to 24 well plates and are immersed in 2 milliliters of MTT extraction buffer. The extraction buffer extracts the MTT reagent from the cells. The 24 well plates are parafilmed, covered and placed in ZIPLOCK bags to reduce evaporation of the extraction buffer. The covered plates are rocked overnight in the dark. Following overnight rocking, the liquid in the EPIDERM skin culture inserts is decanted back into the wells. The contents of each well are mixed and a 200 microliter aliquot is then removed from each well and transferred to a 96 well plate. The optical density (OD) of the samples is measured at 570 nm using a spectrophotometer. Five hundred seventy nanometers is the optimal wavelength at which to measure the reduced form of MTT reagent. This reading is subtracted from a background reading at 650 nm to improve data quality. Percent viability of each test composition + insult relative to the Control + PBS is recorded as the Mean $OD_{\text{test composition + insult}}$ divided by the Mean $OD_{\text{control + PBS}}$; the quotient then multiplied by 100.

EPIDERM skin culture studies were conducted to measure the reduction in IL-1 response between compositions of the invention and a fecal protease-induced irritation. The studies were conducted using polymers that are representative of the invention. The EPIDERM skin culture studies and associated MTT assays were conducted as already described herein and the results are as reported in Table 2. below.

Table 2.

Composition	Polymer Component of Composition	Mean Reduction of Interleukin-1 Alpha (percentage)	Viability (percentage)
A	2% AP-1	40% (5) ; 61% (5)*	95% ; 108%
B	5% AP-1	84% (5)* ; 100% (5)*	93% ; 104%
C	2% AP-3	21% (5) ; 69% (5)	89% ; 103%
D	5% AP-3	24% (5) ; 68% (4)*	93% ; 102%
E	1% AP-4	0% (5) ; 21% (5)	91% ; 97%
F	5% AP-4	15% (5) ; 86% (5)*	96% ; 97%
G	Positive Control, 0.4% Epigallocatechin gallate (green tea component)	48% (5)* ; 78% (5)*	109%; 122%

AP-1 = NARLEX DC-1 C_{12} alkyl polyacrylate polymer available from National Starch and Chemical Co. AP-1-a and AP-1-b have concentrations of 20% and 33%, respectively

AP-3 = ACULYN-R 33 polymer is a solution, 5% by weight, of partially crosslinked acrylate polymer available from Rohm and Haas.

AP-4 = RHEOTHIK 80-11 polymer is a solution, 10% by weight, of high molecular weight poly (sulfonic acid) polymer available from Cognis Corporation.

Two experiments were conducted for each of the compositions. The number of replicates are indicated in parentheses. An asterisk ("*") after a result indicates that the test composition was significantly different from the water + protease control according to the Student's t-test, $p<0.05$. Lower concentrations of polymers in Table 2. above were prepared by diluting the 5% stock compositions in water.

The reduction of IL-1 results were analyzed to statistically identify "outlier" results. The EPIDERM skin culture is known to be variable with the variability attributed to differences in the culture, variation in the application of treatment and other uncontrollable factors. A statistical analysis technique was applied to identify when a result abnormally deviated from the rest of the data set. The irritation values were first converted to Log10 in order to make them more Gaussian (bell curve-shaped). After conversion, the values were analyzed for high or low value outliers; subsequently, the values were analyzed with a student's t-test to identify significant differences from the "control". The statistical analysis used to identify "outliers" is described on page 460 of the book, "Statistical Methods in Research and Production" edited by Owen L. Davies and Peter L. Goldsmith, published by Longman Group Limited, fourth revised edition published in 1984.

The IL-1 reduction results of Table 2. show that the compositions of the invention provide a skin protectant effect as evidenced by a reduced irritation response. In addition

to the beneficial effects of anionic decoupling polymers described in Table 2., cationic decoupling polymers also show a positive effect on protection of the skin when skin is exposed to fecal proteases. Additional EPIDERM skin culture studies were conducted with cationic polymers as well as anionic polymers and the results are provided in Table 3. below. These results are for a fecal protease-induced irritation.

Table 3.

Composition	Polymer Component of Composition	Mean Reduction of Interleukin-1 Alpha (percentage)	Viability (percentage)
A	5% AP-1	88% (5)* ; 82% (5)*	106% ; 95%
B	5% AP-2	0% (5) ; 0% (5)	93% ; 100%
C	3.3% CP-1	52% (5) ; 0% (5)	83% ; 104%
D	2% CP-2	18% (5) ; 11% (5)	91% ; 93%
E	5% DTDMAC	12% (5) ; 29% (5)	90% ; 102%
F	Positive Control, 0.4% Epigallocatechin gallate (green tea component)	100% (5)* ; 43% (5)*	111% ; 110%

AP-1 = NARLEX DC-1 C_{12} alkyl polyacrylate polymer available from National Starch and Chemical Co.

AP-2 = ACLOSPERSE 325 C_{12} alkyl polyacrylate polmer.

CP-1 = is a chitosan polymer with an acetic acid ion.

CP-2 = JAGUAR C-13 is a cationic polysaccharide polymer with a chloride ion available from Rhodia, Inc in Cranberry, New Jersey.

DTDMAC = is ditallow dimethylammonium chloride polymer with a chloride ion.

Two experiments were conducted for each composition and the number of replicates is indicated in parentheses. The asterisks ("*") in Table 3. indicate compositions having a significant difference from a water + protease insult using the Student's t-test, $p<0.05$. These results were also subjected to the statistical outlier test. The results of Table 3. show that cationic decoupling polymers as well as anionic decoupling polymers have efficacy for reducing the irritation response of the skin when skin is exposed to a fecal protease insult. Both anionic and cationic decoupling polymers have a protective effect when the skin model is exposed to bile acid-induced irritation. CP-2 did not show activity but it is believed that CP-2 would show activity if provided in a formula that would not interfere with its negative surface charges. EPIDERM skin culture studies were conducted to measure irritation in response to a bile acid insult. The results are provided in Table 4. below.

Table 4.

Composition	Polymer Component of Composition	Mean Reduction of Interleukin-1 Alpha (percentage)	Viability (percentage)
A	5% AP-1	50% (5)*	95%
B	5% AP-2	51% (5)*	100%
C	3.3% CP-1	76% (5)*	104%
D	2% CP-2	3% (5)	93%
E	5% DTDMAC	75% (5)*	102%

AP-1 = NARLEX DC-1 C_{12} alkyl polyacrylate polymer available from National Starch and Chemical Co.

AP-2 = ACLOSPERSE 325 C_{12} alkyl polyacrylate polmer .

CP-1 = is a chitosan polymer with an acetic acid ion.

CP-2 = JAGUAR C-13 is a cationic polysaccharide polymer with a chloride ion.

DTDMAC = is ditallow dimethylammonium chloride polymer with a chloride ion.

One experiment was run for each composition and the number of replicates is indicated in parentheses. The asterisks ("*") in Table 4. indicate compositions having a significant difference from a PBS + bile acid insult using the Student's t-test, $p<0.05$. The results were subjected to the statistical outlier test described above. The results in Table 4. indicate that the polymers of the invention also have a protectant effect against bile acid-induced irritations. These results support the belief that compositions of the invention provide a benefit to the skin by reducing the skin's irritation response to biological-type insults.

While the invention has been described in detail with respect to the specific aspects thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of, and equivalents to these aspects. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.